

REMARKS

Claim 14-26 are pending in this application. Claim 1-13 were previously canceled. With this Reply, Applicants have amended claims 14-19, 21-23, and 25 and added new claims 27-29. Several of the pending claims have been rejected under § 101, § 112 and/or § 102. Applicants respectfully request reconsideration of the application in view of the amendments and the following remarks, which address each of the rejections and objections raised in the Office Action.

Claim Amendments

Claim 14 has been amended to clarify the claim by correcting minor grammatical and nomenclature errors. In addition, the claim has been amended to modify the definition of various substitutions and to delete the term “prodrugs.” Support for these changes is found, for example, on pages 17-37 of the specification as filed.

Claim 15 has been amended by correcting the form of a dependent claim and by deleting the term “prodrugs.”

Claim 16 has been amended by correcting the form of a dependent claim, by replacing the reference to formula (II) with a reference to formula (XIX), and by deleting the term “prodrugs.”

Claims 17-19 have been amended to correct the form of a dependent claim, to delete each occurrence of the term “inosine,” to insert at line 3 the species “2,6-diaminopurine” and to specify that derivatives refer to a heterocyclic ring substituted with one or more substituents independently selected from the group consisting of halogen, hydroxyl, amino and C₁₋₆ alkyl. Support for these changes is found, for example, on page 9, line 23, and on page 10, lines 4-7, of the application as originally filed.

Claim 21 has been amended by correcting the form of a dependent claim, and by correcting compound nomenclature by replacing “threose” with “threofuranose” at each occurrence. The latter correction is supported by the structural formulae of the corresponding compounds shown in Figure 1.

Claims 22-23 have been amended by deleting the words “prevention or” and by inserting the words “in need thereof.”

New claim 27 has been added and is directed to a species of the general formula (XXVIII), which is described at page 79, line 14, of the application as originally filed and being structurally shown in different stereoisomeric forms on each of Figures 1 and 3-12.

New claim 28 has been added and is directed to a family of compounds described from page 17, line 12, to page 18, line 22, of the application as originally filed.

New claim 29 has been added and is directed to compounds described at page 18, lines 23-24, of the application as originally filed.

No new matter has been added by these amendments.

Objection to the Abstract

The Office Action objects to the Abstract, asserting that it “is too brief, not mentioning all of the various part of the instant claimed subject matter.” First of all, Applicants would like to point out that the abstract was over 120 words long, and has been amended to be over 130 words long - not far from the maximum 150 words allowed for an abstract - so it is hardly short. Furthermore, M.P.E.P. § 608.01(b) merely requires that the abstract set forth “the *general* nature of the compound or composition should be given as well as its use.” Applicants respectfully submit that the present Abstract satisfies this requirement. In particular, the Abstract identifies the general nature of the compounds by stating that the invention features “phosponalkoxy-substituted nucleosides.” In addition, the Abstract sets forth several uses of these compounds by specifying that the compounds have “HIV (Human Immunodeficiency Virus) replication inhibiting properties” and can be used to treat HIV infection as well as other viral infections. Accordingly, Applicants disagree with the Office Action’s assertion that the Abstract is not sufficient; however, in an attempt to address the Examiner’s concerns, Applicants have amended the Abstract in order to add further details concerning the nature of the compounds. Support for the amendment to the Abstract is found, for example, on page 1, lines 4-11, of the application as originally filed. Applicants respectfully submit that this objection may now be withdrawn.

The Drawings

The Office Action indicates that formal drawings will be required when the application is allowed. In addition, the Office Action asserts that the “Brief Description of the Drawings” section is too brief. As suggested by the Examiner, Applicants have amended the specification to

provide a separate description for each drawing. Support for this amendment is found, for example, on pages 57-71 of the application as originally filed.

Cross-Reference to Related Applications

The Office Action at page 2 asserts that the application fails to contain a “Cross-Reference to Related Applications” section as the first paragraph of the disclosure. However, Applicants would like to point out that a “Cross-Reference to Related Applications” section was added to the specification as part of the Amendments to the Specification contained in the Preliminary Amendment of September 1, 2006. The objection should, therefore, be withdrawn.

Objection to the Specification

The specification has been objected to because the word “compound” is misspelled as “comound” at page 97, line 12. Applicants have amended the specification to correct this misspelling, as well as various other typographical and grammatical errors. This objection may now be withdrawn.

Rejection Under 35 U.S.C. § 101

Claims 22 and 23 stand rejected under 35 U.S.C. § 101. The Office Action asserts that these claims lack a demonstrated utility or operable utility in connection with the term “prevention” because the specification fails to adequately establish that the claimed methods are capable of preventing any viral invention, including HIV. Applicants have amended claims 22 and 23 to remove the term “prevention.” This rejection may now be withdrawn.

Claims 20 and 26 also stand rejected under 35 U.S.C. § 101. The Office Action asserts that the definition of the variable “V” and “silyl” read on structural alternatives wherein Si-H bonds are present, thereby rendering the compounds pyrophoric. The Office Action therefore concludes that a substantial portion of the claimed compounds appear to lack reasonable utility for the intended purpose. Applicants respectfully traverse this rejection.

None of the silyl protecting groups illustrated throughout the specification, especially from page 58 to page 64, in particular trimethylsilyl and tert-butyl dimethylsilyl, includes a Si-H bond, and the skilled person would not recognize a silyl group with a Si-H bond as capable to act

as a protecting group. Therefore, we respectfully disagree with the Examiner that the subject matter of claims 20 and 26 encompasses compounds which may lack utility. This rejection should therefore be withdrawn.

Rejection Under 35 U.S.C. § 112, First Paragraph

Claims 22, 23, and 25 stand rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors had possession of the claimed invention at the time the application was filed. In particular, the Office Action asserts that the instant disclosure “does not include any tests establishing that any of the instant compounds is capable of preventing any viral infection.” As discussed above, Applicants have amended claims 22 and 23 to remove the term “prevention.” With respect to claim 25, the term “antiviral agent” has been replaced with the phrase “retroviral enzyme inhibitor.” In addition, Applicants note that this is a composition claim and does not specifically recite the prevention or treatment of a viral disease. Applicants therefore respectfully submit that this ground for rejection should be withdrawn.

Claims 14-20 and 22-26 stand rejected under 35 U.S.C. § 112, first paragraph, as lacking enablement in the specification. In particular, the Office Action asserts that the specification, “while being enabled for the synthesis for a small number of nucleoside and nucleotide analogues wherein linker-attached 3-phosphonyl-L-threofuranosyl moieties have replaced ribo- or 2'-deoxyribofuranosyl substituents ... does not reasonably provide enablement for the vast array of compounds claimed herein.” Applicants respectfully traverse this rejection as applied to the amended version of the claims.

Applicants submit that, due to the amendments brought into claim 14, this rejection should be withdrawn. By amending the definition of R¹ and R², and by specifying that R³, R⁷ and R⁸ are each hydrogen, it can readily be seen that the subject matter claimed is commensurate in scope with what is described in detail at pages 57 to 96, and structurally shown in Figures 1 to 15. The specification thus enables the skilled person to achieve a desired stereoisomer without undue experimentation. For example, although all Figures 1 to 15 show compounds wherein X₁ is oxygen (furanoses), it is clear to the skilled person that the corresponding compounds wherein

X₁ is sulfur can readily be prepared by the same synthetic routes but starting from the corresponding dihydro-dihydroxy-thiophenone.

The Office Action also asserts that the presence of indefinite terms such as “derivatives” (claims 17-19) or “Phos” (claim 20) calls into question the enablement of these claims. With respect to the term “derivatives,” Applicants have amended claims 17-19 to more specifically identify the nature of the derivatives by using the definition given in the specification. This rejection as applied to claims 17-19 should therefore be withdrawn.

With respect to the term “Phos” used in claim 20, Applicants respectfully disagree with the arguments in the Office Action. This term is defined at page 9, lines 10-16, in a manner which is clear and complete and makes reference to terminology or nomenclature in accordance with IUPAC rules. This definition merely corresponds to the phosphorus-containing group present at position 3 of the compounds represented by the structural formula (II) in claim 14, or the compounds represented by the structural formula (I) in claim 28. Therefore, this rejection should also be withdrawn with respect to claim 20.

Rejection Under 35 U.S.C. § 112, Second Paragraph

Claims 14-23 are rejected under 35 U.S.C. § 112, second paragraph, as failing to particularly point out and distinctly claim the subject matter. Applicants respectfully traverse this rejection as applied to the amended version of the claims.

Applicants have amended claims 14-23 to address most of the indefiniteness issues raised by the Examiner. With respect to those indefiniteness issues not dealt with by amendment, Applicants have the following comments.

The assertion in the Office Action concerning claim 14 regarding oxygen and sulfur not being elements is not understood. It is clear for instance from considering formulae (I), (II) and (XIX) that each X acts as a linking moiety between carbon atoms. By reciting that the heteroatom(s) is (are) located in the hydrocarbon chain, amended claim 14 makes it clear that that these substituent moieties have a terminal substituent. It is thus conventional in the art to designate these substituent moieties as atoms. The hydrocarbon chain being made up of repeating –CH₂– units, it is also clear to the skilled person that when a nitrogen atom is contained in the hydrocarbon chain, the –CH₂– unit is replaced with a –NH– unit.

With respect to the terms “solvates” and “stereoisomers,” Applicants point out that these have been extensively defined at page 15, lines 4-19, of the specification in a manner which is conventional in the art. Since the claims are to be read in light of the specification, it is not necessary to insert this definition into the claims.

With respect to the terms “heterocyclic” and “heterocyclic-alkyl,” Applicants point out that these have been extensively defined from page 12, line 9, to page 14, line 6, of the specification in a comprehensive manner which is conventional in the art. Since the claims are to be read in light of the specification, it is not necessary to insert this definition into the claims.

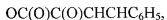
With respect to the objected term “Phos” in claim 20, Applicants submit that this term is definite for the reasons discussed above in connection with the previous rejection.

For all the above reasons, Applicants submit that the indefiniteness rejections should be withdrawn.

Rejection under 35 U.S.C. § 102 (b)

Claim 26 is rejected under 35 U.S.C. § 102(b) as being anticipated by Dujardin et al (PTO-1449 ref. AR). The Office Action asserts that certain compounds on page 1557 of Dujardin each anticipate the structure of claim 26. Applicants respectfully disagree.

For example, in compounds **8g** and **8h** of Dujardin, position 3 of the furanose unit is attached to a group with the formula:



i.e., a keto-ester group, whereas the structural formula (XXVIII) of claim 26 requires U to be an acyl group. An acyl group is conventionally defined at page 14 lines 7-14 of the specification as “a carbonyl group directly attached to an alkyl, alkenyl, aryl, arylalkenyl ... group.” It is clear to the skilled person that the keto-ester group of Dujardin does not meet this standard definition of an acyl group, since the carbonyl group is not directly attached to a hydrocarbonyl group. Consequently, this rejection should also be withdrawn.

CONCLUSION

In view of the forgoing Amendment and Remarks, Applicants submit that amended claims 14-26 and new claims 27-29 are in condition for allowance, and such action is respectfully requested.

Transmitted herewith is a Petition to extend the period for replying to the Office Action for one month, to and including April 5, 2010, and an authorization to charge the required extension fee to Deposit Account No. 03-2095.

If there are any additional charges or any credits, please apply them to Deposit Account No. 03-2095.

Respectfully submitted,

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/Sean J. Edman/
Sean J. Edman
Reg. No. 42,506

Clark & Elbing LLP
101 Federal Street
Boston, MA 02110
Telephone: 617-428-0200
Facsimile: 617-428-7045